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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,459	03/10/2000	George Liang King	10276-026001	5799

7590 07/30/2002
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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/524,459

Applicant(s)

KING, GEORGE LIANG

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16 and 18-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-3, 5-16 and 18-29 are pending.
2. Claims 1-3, 5-16 and 18-29 are rejected.

Response to Arguments

3. Applicant's arguments filed April 16, 2002 have been fully considered but they are not persuasive. Applicant makes the following allegations. First, applicants argue that Sitter et al. do not teach of a peritoneal dialysis fluid that includes a specific inhibitor or PKC or a method of making a peritoneal dialysis fluid. In fact, applicant states that Sitter merely disclose in vitro experiments designed to evaluate the effect of D-glucose on intraperitoneal prostaglandin E₂ (PGE₂) levels.

4. Both instant claim 16, which is directed to a peritoneal dialysis fluid, which comprises a specific inhibitor of a PKC and claims 23-27 are essentially directed to methods of using PKC inhibitors in peritoneal dialysis fluids. The prior art reference of Sitter et al. teach of a study to evaluate the effect of D-glucose, which is widely used in commercially available peritoneal dialysis fluids, on the production of prostaglandins, specifically PGE₂. Sitter et al. also disclose in this study that with the presence of the specific kinase C (PKC) inhibitor of Ro 31-8220 the increased PGE₂ synthesis was completely stopped. Sitter et al. provide motivation to the skilled artisan to incorporate a specific kinase C (PKC) inhibitor to peritoneal dialysis fluids because of the showing from Sitter et al., which is that the increased PGE₂ synthesis was completely stopped

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while in the presence of a specific kinase C (PKC) inhibitor. For these reasons, one having ordinary skill in the art would be motivated from the teachings of Sitter et al. as well as those of Hu et al. which teach of the fact that bisindolymaleimide is a highly selective PKC inhibitor, (see abstract) to incorporate specific kinase C (PKC) inhibitors in peritoneal dialysis fluids and to treat individuals so that the peritoneal dialysis fluids would be more effective and less harmful without the effects caused by the increased PGE₂ synthesis due to D-Glucose present in the peritoneal dialysis fluid.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 5-16 and 18-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the PKC inhibitors of bisindolymaleimide, does not reasonably provide enablement for other types of PKC inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. All questions of enablement are evaluated against the claimed subject matter. The question asked by one skilled in the art is whether everything within the scope of the claim is enabled. The instant claims cover all compounds having the pharmaceutical property of being known descriptively as a specific inhibitor of PKC. Accordingly, the instant specification only provides guidance

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and support for the bisindolylmaleimide compounds. The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). One does not look to the claims but to the specification to find out how to practice the invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-7 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). Due to the unpredictability in the art, the state of the art and the lack of working examples for compounds other than those bisindolylmaleimide compounds which are disclosed in the instant specification, one skilled in the art is subjected to an undue experimentation in order to determine the other compounds which are supported by the pharmaceutical property of being known as specific PKC inhibitors.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. The rejection of claims 16 and 18-29 under 35 U.S.C. 103(a) as being unpatentable over Sitter et al. in view of Hu et al. is maintained and repeated for both the above-stated and reasons of record. The prior art reference of Sitter et al. teach of a study to evaluate the effect of D-glucose, which is widely used in commercially available peritoneal dialysis fluids, on the production of prostaglandins, specifically

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PGE₂. Sitter et al. also disclose in this study that with the presence of the specific kinase C (PKC) inhibitor of Ro 31-8220 the increased PGE₂ synthesis was completely stopped. Sitter et al. provide motivation to the skilled artisan to incorporate a specific kinase C (PKC) inhibitor to peritoneal dialysis fluids because of the showing from Sitter et al., which is that the increased PGE₂ synthesis was completely stopped while in the presence of a specific kinase C (PKC) inhibitor. For these reasons, one having ordinary skill in the art would be motivated from the teachings of Sitter et al. as well as those of Hu et al. which teach of the fact that bisindolymaleimide is a highly selective PKC inhibitor, (see abstract) to incorporate specific kinase C (PKC) inhibitors in peritoneal dialysis fluids and to treat individuals so that the peritoneal dialysis fluids would be more effective and less harmful without the effects caused by the increased PGE₂ synthesis due to D-Glucose present in the peritoneal dialysis fluid.

Subject Matter Free of the Prior Art

9. Claims 1-15 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
July 26, 2002